

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

### 21 CFR Part 358

[Docket No. 2002N-0058]

RIN 0910-AA01

### Pediculicide Drug Products for Over-the-Counter Human Use; Amendment of Final Monograph

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final rule amending the final monograph (FM) for over-the-counter (OTC) pediculicide drug products to revise labeling for the statement of identity, warnings, directions, and other required statements. Pediculicide drug products are used for the treatment of head, pubic (crab), and body lice. FDA is issuing this final rule as part of its ongoing review of OTC drug products after considering public comment on its proposed regulation and all relevant data and information that have come to the agency's attention.

**DATES:** *Effective Date:* This final rule is effective June 30, 2005.

*Compliance Dates:* The compliance date for OTC pediculicide drug products with annual sales less than \$25,000 is January 3, 2006. The compliance date for all other OTC pediculicide drug products is June 30, 2005.

#### FOR FURTHER INFORMATION CONTACT:

Michael T. Benson, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

#### SUPPLEMENTARY INFORMATION:

#### I. Background

In the *Federal Register* of December 14, 1993 (58 FR 65452), FDA published a final rule in the form of a FM in part 358 (21 CFR part 358, subpart G) establishing conditions under which OTC pediculicide drug products are generally recognized as safe and effective. The effective date of the final rule was December 14, 1994. Since that time, FDA has determined that labeling in the statement of identity, warnings, directions, and certain other required statements in the pediculicide monograph should be amended.

In the *Federal Register* of March 17, 1999 (64 FR 13254), FDA published a final rule that established a standardized format and standardized

content requirements for OTC drug product labeling in § 201.66 (21 CFR 201.66). In that same final rule (64 FR 13254 at 13296), FDA amended the FM for OTC pediculicide drug products and removed the requirement in § 358.650(d)(1) that the direction "Important: Read warnings before using" be printed in all capital letters. The sentence now needs to appear in boldface type with only the word "Important" and the first letter in the word "Read" capitalized.

In the *Federal Register* of May 10, 2002 (67 FR 31739), FDA published a proposed rule to amend the FM for OTC pediculicide drug products to revise labeling for the statement of identity, warnings, directions, and other required statements to increase the probability of treatment success with these products. In response to that proposal, one OTC trade association and a professor of clinical toxicology submitted comments, which FDA is responding to in this document.

#### II. The Agency's Conclusion on the Comments

##### A. Comments in Agreement with the Proposed Rule

(Comment 1) One comment agreed completely with the proposed recommended label changes. Another comment agreed with the following proposed changes:

- New statement of identity (i.e., remove "pediculicide" and just state "Lice treatment" by itself);
- Simplified indications under the heading "Uses";
- Formatting changes using subheadings (i.e., "Do not use," "Ask a doctor before use," "When using this product," and "Stop use and ask a doctor if");
- Bulleted statements under each subheading.

##### B. Comments with Labeling Recommendations

(Comment 2) One comment contended that the proposed additional directions are too extensive to fit on pediculicide product carton labels. The comment stated that lengthy, detailed directions for environmental control of lice and combing the hair and "other information" would be more appropriately provided in a package insert than on a carton label. The comment agreed that essential treatment directions should be on the outer label, but that consumers do not need to be able to read the entire detailed instructions at the point of purchase. The comment recommended that the outer package have a statement directing

consumers to an insert for more complete directions. The comment suggested "See brochure inside for other important information to help get rid of lice." The comment also added that a statement about use of a comb should be optional on the outer label and should instruct consumers to see the package insert for complete directions and could incorporate a reference to a comb provided in the package.

FDA considered the length of the additional directions and provided in the May 10, 2002 proposal (§ 358.650(e)) that the detailed information required under the heading "Other information" may appear in a package insert. If that occurs, the "Other information" section on the outer label only needs to include a statement that refers to the package insert for additional information. The information about use of a comb is part of the essential treatment directions (§ 358.650(d)(5)) and, thus, needs to appear on the outer label. If the product does not have a comb with it, consumers would need to know at the point of purchase that they may also need to purchase a special comb to use with the product. FDA is clarifying the introductory paragraph in § 358.650(e) to read that if a package insert is used, the "Other information" section on the outer label shall include a statement referring to the package insert for additional information.

(Comment 3) One comment recommended that the directions proposed in § 358.650(d)(4)(i) or (d)(4)(ii), (d)(6), (d)(7), and (d)(8) appear both on the outer package label and in the package insert. The information includes the following provisions:

- Application directions for shampoo or nonshampoo products,
- Directions for a followup treatment,
- Instructions to see doctor if the infestation continues,
- Instruction to consult a doctor for children under 2 years of age.

FDA agrees with the comment. Directions that appear on the outer package label in accordance with § 201.66(c) may be restated in a package insert.

(Comment 4) One comment disagreed with the agency's change from 2 weeks to 4 weeks for the time items that cannot be washed should be sealed in a plastic bag (§ 358.650(e)(1)). The comment stated that FDA gave no rationale for doubling the time and pediculicide manufacturers know of no evidence showing more than 2 weeks is needed to prevent reinfestation.

FDA initiated the change for sealing items that cannot be washed in a plastic bag from 2 to 4 weeks for greater assurance of preventing head lice